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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/939,656

08/28/2001

Arthur E. Uber III

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04/29/2004

VI/98-013.FWC.C.

EXAMINER

DESANTO, MATTHEW F

GREGORY L BRADLEY
MEDRAD INC
ONE MEDRAD DRIVE
INDIANOLA, PA 15051

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 04/29/2004

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/939,656

Applicant(s)

UBER, ARTHUR E.

Examiner

Matthew F DeSanto

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-18 and 63-91 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-18 and 63-91 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>16</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 13-18, 64-67, 69, and 72-80 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Pattillo et al. (USPN 4,937,194).

Pattillo et al. discloses an injection device with a first fluid source (10B), a second fluid source (142a or 138), a fluid path, and a mixing element (134, and the Y-connector [Column 8, lines 46-53]); as well as a metering device, a control unit, and a fluid assurance device. The “reusable portion” being the flow path from the mixing element down. The “disposable portion” being the fill bags (134a). (Figures 2, 5 and entire reference)

3. Claims 13-16, 64, 65, 66, 69, 72-75, 78, and 79 are rejected under 35 U.S.C. 102(b) as being anticipated by Roberts (USPN 4,754,786).

Roberts discloses an injection device with a first fluid source, a second fluid source, a fluid path, and a mixing element; as well as a metering device, a control unit, and a fluid assurance device. The “reusable portion” being the flow path from the

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mixing element down. The "disposable portion" being the fill bags. (Figures 5, 6 and entire reference)

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 13-18, 63-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thompson et al. (USPN 4,710,166), and further in view of Wortich (USPN 4,750,643).

Thompson et al. discloses an injection device with a first fluid source and a second fluid source, as well as a mixing device (static and Y-connector), a pump or metering device, a control unit, valves and an electronic interface. (See Figures 1, and 11), but fails to disclose a fluid assurance device and multiple reusable and disposable portions.

Wortich discloses a sterile fluid dispensing system that comprises a fluid source, a fluid assurance element, multiple disposable portions, and a reusable flow path. (Figure 1 and entire reference)

At the time of the invention it would have been obvious for one of ordinary skill in the art to combine Thompson et al. with Wortich because Wortich teaches the economic benefit of using the setup disclosed by Wortich as well as the ability to infuse fluid into multiple patients.

6. Claims 13-18, 63-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Orkin et al. (USPN 4,925,444).

Orkin et al. discloses an injection device with a first fluid source and a second fluid source, as well as a mixing device, a pump or metering device, a control unit, valves and an electronic interface, a fluid assurance element and one reusable portion and a disposable flow path, (Figure 1 and entire reference), but fails to disclose multiple reusable and disposable portions.

Wortich discloses a sterile fluid dispensing system that comprises a fluid source, a fluid assurance element, multiple disposable portions, and a reusable flow path. (Figure 1 and entire reference)

At the time of the invention it would have been obvious for one of ordinary skill in the art to modify Orkin et al. because Wortich teaches the economic benefit of using the setup disclosed by Wortich as well as the ability to infuse fluid into multiple patients.

The examiner would also like to note that the multiplication of the infuse lines is a mere duplication of parts and has been indicated by the courts as taking only routine skill in the art, which would further support the 103 Rejections made above.

Response to Arguments

7. Applicant's arguments with respect to claims 13-19 have been considered but are moot in view of the new ground(s) of rejection.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F DeSanto whose telephone number is 1-703-305-3292. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 1-703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Matthew DeSanto
Art Unit 3763
April 19, 2004



BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700